MOTION FILED
AUG 3 1989

No. 89-12

IN THE

SUPREME COURT OF THE UNITED STATES

October Term, 1988

CARITA RICHARDSON, BY
S. & E. RICHARDSON, GUARDIANS, et al.,
Petitioners,

v.

RICHARDSON-MERRELL, INC.,
Respondent.

MOTION FOR LEAVE TO FILE BRIEF AS AMICUS CURIAE

AMICUS CURIAE BRIEF OF THE ASSOCIATION OF BIRTH DEFECT CHILDREN

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MOTION OF ASSOCIATION OF BIRTH DEFECT CHILDREN TO FILE AMICUS CURIAE

1. Petitioner is the Association of Birth Defect Children, a non-profit organization representing children with severe birth defects.

2. Petitioner moves this Court to allow the filing of the attached Amicus Curiae Brief.

3. The Brief sets forth facts and legal argument relevant to the disposition of this case, and bears directly upon the issue of Federal Rule of Evidence 703 relating to "Basis of Opinion Testimony by Experts."

4. The Amicus Brief addresses state court cases such as Blum vs. Merrell Dow Pharmaceuticals, Inc., No. 01867 and No. 02016 Phila. 1988 (Pa.Super. June 14, 1989) and Oxendine v. Richardson-Merrell, 506 A.2d 1100 (D.C. 1986), in which the courts did not grant judgment n.o.v.. on the basis that there was insufficient sufficient evidence to create a jury issue based upon expert testimony.

5. In the interests of justice, the Amicus Curiae Brief of the Association of Birth Defect Children, representing children with birth defects similar to those of Carita Richardson, should be considered by this Court, in its decision on the granting of Carita Richardson's Petition for a Writ of Certiorari.

6. Amicus Association of Bendectin Children requested consent to file this brief which was refused by Respondent, Richardson-Merrell, Inc.

Respectfully Submitted,

Thomas R. Kline, Esquire

Date: August 3, 1989

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INTEREST OF THE AMICUS

The Association of Birth Defect Children is a non-profit organization formed in 1982 to serve as an international emotional and informational support system for families of children with birth defects. The Association provides newsletters and information to families as well as medical, educational and social service personnel.

By way of this amicus curiae brief, the Association seeks to protect the interest of all children who suffered or will suffer from exposure to any dangerous chemicals or

drugs. The decision of the District of Columbia Circuit Court, if allowed to stand, would seriously curtail the admissible evidence in many suits. Many similarly situated children, not only those suffering from their mother's use of Bendectin, will be denied their right to a jury trial pursuant to the Seventh Amendment to the Constitution of the United States.

SUMMARY OF THE ARGUMENT

The Circuit Court below improperly applied Federal Rule of Evidence 703, thereby overturning a valid jury verdict based upon valid expert testimony. Medical testimony, in other Bendectin trials in the state and federal courts in the United States, was deemed sufficient to create a jury issue. The District of Columbia Court of Appeals in this case, in reaching a contrary result erred first in its refusal to consider the testimony in its entirety, and second in its incorrect application of Rule 703. The Court below acted as both scientist and jurist, incorrectly taking away the traditional jury

function, as a matter of law, and depriving plaintiff, a severely damaged child, to her right to a trial by jury under the Constitution of the United States.

In two state court opinions, Oxendine v. Merrell Dow Pharamaceuticals, Inc., 506 A.2d 1100 (D.C. 1986) and Blum v. Merrell Dow Pharmaceuticals, No. 1027 C.C.P. Phila., May 12, 1988, rev'd on other grounds, Nos. 01867 and 02016 Philadelphia 1988 (Pa.Super. June 14, 1989), petition for allocatur and cross-petition for allocatur filed, the respective appeals courts refused to grant judgment n.o.v. against a verdict rendered by a jury upon scientific and

medical evidence regarding the drug Bendectin. So too, in two cases in the United States District Court for the Eastern District of Pennsylvania, the evidence was sufficient to create a jury issue. And, in the federal multidistrict Bendectin trial, the Sixth Circuit Court of Appeals held that the scientific evidence could have supported a plaintiff's verdict.

The District of Columbia Circuit Court below erred in its stripping of the jury from its proper function and in using Rule 703 to justify the result.

ARGUMENT

The Decision of the Court Below Based Upon Federal Rule of Evidence 703 Was Illogical And Irrational In Concluding That The Expert Testimony In This Bendectin Case Was Insufficient To Present A Jury Issue.

In contrast to the decision of the court below based upon Federal Rule of Evidence 703, the appellate courts of two non-federal jurisdictions have thoroughly reviewed the evidence presented in two lengthy Bendectin trials, and have apparently reached the conclusion that the evidence formed an adequate basis for a verdict in favor of the plaintiff. The first case, Oxendine v. Merrell Dow Pharamaceuticals, Inc., 506 A.2d 1100

(D.C. 1986), was decided in the local courts of the District of Columbia in 1986. Subsequently, in 1988, the Superior Court of Pennsylvania rendered the decision of Blum v. Merrell Dow Pharmaceuticals, Inc., Nos. 01867 and 02016 Philadelphia 1988 (Pa. Super. June 14, 1989), petition for allocatur and cross petition for allocatur filed. In reviewing these decisions it is clear that expert testimony in a medical and scientific case involving a prescription drug product qualifies as sufficient evidence creating a factual issue for jury determination either

under state or federal rules of evidence.

In Oxendine, the plaintiff, who suffered severe limb deformities, brought an action against Merrell Dow alleging that her mother's use of the drug Bendectin was the cause of her deformities. The trial, which included the testimony of eighteen witnesses, lasted approximately three weeks and ultimately resulted in a jury award of $750,000.00 in compensatory damages. Merrell Dow, thereafter, filed a motion for judgment n.o.v. or, in the alternative, for a new trial. The trial court in granting the motion stated that "[i]t is clear to the Court from review of the evidence adduced at

the trial of this action that no conclusion one way or another can be drawn from any of the... relied upon bases, respecting whether Bendectin is a human teratogen." Oxendine, 506 A.2d at 1103.

On appeal, the trial court's granting of judgment n.o.v. was reversed. The District of Columbia Court of Appeals reviewed the testimony submitted by the experts, which consisted of various studies analyzing the teratogenic effects of Bendectin. The first of the studies in that case was the chemical structure activity analysis. This enables a pharmacologist to look at the structure of a compound to predict the

outcome of the drug's activity. The second test relied upon was the in-vivo (animal) studies. This produces evidence establishing Bendectin's teratogenic effects on other species. The third test relied upon, the in-vitro (test tube) studies, is particularly valuable for focusing on the specific effect of a drug. The scientist has the ability to separate limb bud cells of animal embryos for the purpose of determining whether the development of the limbs is thwarted by the exposure to a particular drug. Fourth, there are epidemiological studies, which are "the study of the frequency of disease in human populations and the way in which that

frequency varies from one population to another." Oxendine, 506 A.2d at 1107.

Alan Done, M.D., a pediatrician and toxicologist testified as an expert witness in Oxendine that none of the four types of evidence could in and of itself establish that Bendectin had teratogenic effects in humans. However, each separate test result is indicative of the harmful effects of Bendectin on fetuses. For example, the chemical structure activity analysis establishes that doxylamine succinate, which is a component of Bendectin, is a known teratogen in some animals and a suspected teratogen in humans. The in-vitro test, conducted on female rabbits, resulted in mild limb

alterations when minimal doses were administered during pregnancy. Other studies performed on mice, rats, and monkeys further supported Dr. Done's position that Bendectin is a teratogen. The in-vitro tests, performed by a Dr. Hassell, provided data that supported the conclusion that Bendectin interfered with the growth and development of limb bud cells. Finally, the epidemiological studies, would support Dr. Done's conclusion that Bendectin caused severe birth defects. Oxendine, supra.

The trial court, in Oxendine, like the District of Columbia Circuit Court in this case, disregarded the totality of plaintiff's expert

testimony. Rather, the court focused on "[Dr. Done's] inability to conclude that Bendectin was a teratogen on the basis of any of the individual studies which he discussed". Oxendine, 506 A.2d at 1108. In granting the judgment n.o.v.

> [t]he court focused on this fact and concluded that if each type of data, viewed in isolation, was not sufficient to prove that Bendectin caused birth defects, then all of them taken together could not prove it either. Id. at 1104.

The District of Columbia Court of Appeals overruled the decision of the trial court, stating:

> [T]he court erred...in failing to consider the same expert's testimony that all of the studies, taken in combination, did support such a finding as [Dr. Done]

> carefully and repeatedly explained...In ruling on motion for judgment n.o.v., the court must view the evidence as a whole, not in fragments. Like the pieces of a mosaic, the individual studies showed little or nothing when viewed separately from one another, but they combined to produce a whole that was greater than the sum of its parts...Because he fully explained to the jury that his opinion was based on all of the studies, we cannot say that no reasonable juror could reach a verdict in favor of appellant. Id. at 1110. (emphasis in the original).

Therefore, the District of Columbia Court of Appeals reversed the decision of the lower court, and properly reinstated the jury verdict for the plaintiff.

In a Pennsylvania Bendectin case, Blum, supra, both the state trial court

and state appellate court faced the issue of whether the evidence submitted by the plaintiff was sufficient to withstand defendant's post-trial motion for judgment n.o.v. Both courts declined to grant judgment n.o.v. requested by the defendant drug manufacturer. In that case, plaintiff's expert "testified to relying upon the structure/activity of the drug, as well as in vitro, animal and epidemiological studies in reaching his conclusion that Bendectin is a teratogen (causes or increases the risk of birth anomalies) in humans". Blum, No. 01867 and 02016 Philadelphia 1988, Slip Op. at 3. The trial court held that "[v]iewing the aforementioned

evidence...clearly negates any argument that a judgment n.o.v. is warranted." Blum v. Merrell Dow Pharmaceuticals, No. 1027 Slip Op. at 14 (C.C.P. Phila. May 12, 1988), rev'd on other grounds, Nos. 01867 and 02016 Philadelphia 1988 (Pa.Super. June 14, 1989), petition for allocatur and cross petition for allocatur filed. Thus, the Pennsylvania courts dismissed the defendant's claim based upon the sufficiency of plaintiff's evidence.

The District of Columbia Circuit Court in Richardson, in granting a judgment n.o.v., did not address the Blum decision. The Circuit Court did address Oxendine, attempting to distinguish it by the circuitous

application of the Federal Rule of Evidence Rule 703, which provides:

> The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the factors or data need not be admissible in evidence.

In construing this Rule, the Court below emphasized that "the grounds relied on by an expert must be 'a type reasonably relied upon by experts in a particular field.'" Richardson v. Richardson-Merrell, Inc. 857 F.2d 823, 829 (D.C. Cir. 1988), quoting, Fed.R.Evid. 703. The court then centered its entire analysis around its

own perception of the credibility of evidence. At the start, the court recognized that the possible teratogenic effects of Bendectin are "scientific in nature, and it is to the scientific community that the law must look for the answer." Id. at 829. However, the court then provided its own scientific answer setting itself up as jurist and scientist as well. It criticized the Oxendine court because the latter "did not address the significance of certain evidence bearing upon the current state of scientific knowledge [and had] judicially reopened an esoteric 20-year-old controversy which is by now essentially settled within the

scientific community." Richardson, 857 F.2d at 825 n.9. This demonstrates that the Richardson court arbitrarily concluded that a minority view is of no merit. However, the Fifth Circuit, in Osborn v. Anchor Laboratories, 825 F.2d 908, 915 (5th Cir. 1987), cert. denied, 108 S.Ct. 1476)(1988), provided that:

> An expert's opinion need not be generally accepted in the scientific community before it can be sufficiently reliable and probative to support a jury finding...What is necessary is that the expert arrived at this causation opinion by relying upon methods that other experts in his field would reasonably rely on in forming their own, possibly different opinions, about what caused the patient's disease. (Emphasis in the original)

In Oxendine, several of the defense experts conceded that plaintiff's expert's methodology was proper even though they chose alternative methods. But the Circuit Court in Richardson stated that "whether an expert's opinion has an adequate basis, and whether without it an evidentiary burden has been met are matters of law for the court to decide." In Richardson, 857 F.2d at 829, even though the District of Columbia Court of Appeals tactily recognized that the scientific evidence is the legitimate subject of debate before a jury, the court then flatly stated that "[w]e conclude that Dr. Done's opinion lacks an adequate basis". Id. at 829. The

court, therefore, illogically and incorrectly stripped the jury of its function in the face of a sufficient legal record upon which the jury rendered its decision.

By invalidating the sufficiency of the testimony, the court contradicted the fundamental doctrine that establishes that:

> Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge, whether he is ruling on a motion from summary judgment or for a directed verdict. Anderson v. Liberty Lobby, 477 U.S. 242, 255 (1986).

The ruling in Anderson is premised upon the notion that:

> Judges, both trial and appellate, have no special competence to resolve the complex and refractory causal issues raised by the attempt to link low level exposure to toxic chemicals with human disease. On questions such as these, which stand at the frontier of current medical and epidemiological inquiry, if experts are willing to testify that such a link exists, it is for the jury to decide whether to credit such testimony. Oxendine, 506 A.2d at 1104, quoting, Ferebee v. Chevron Chemical Co., 736 F.2d 1529, 1534 (D.C. Cir.), cert.denied, 469 U.S. 1062 (1984).

However, under the contradictory reasoning set forth by the District of Columbia Circuit Court in this case, the judge had the final say as to what the "scientific community" would have determined, clearly usurping the jury's function as a fact finder.

With respect to the scientific evidence in Bendectin cases, it has been stated in a federal Bendectin case by Senior Judge Charles Weiner of the Eastern District of Pennsylvania that where the "plaintiff's experts say 'it tis' and the defendant's experts say 'tis not'," Rosen, et al. v. Richardson-Merrell, Inc., No. 82-0513, Slip Op. at 12 (E.D. Pa. July 22, 1987), then a classic jury issue has been created. Judge Weiner made this statement in an Opinion rendered after hearing two Bendectin jury trials to verdict. See, Rosen, supra; Lanzilotti v. Merrell-Dow Pharmaceuticals, Inc., No. 82-0193 (E.D. Pa. 1986). Similarly, in In re Richardson-Merrell,

Inc. Bendectin Product Liability Litigation, MDL No. 486, 857 F.2d 290 (6th Cir. 1988), cert. denied (1989), in an Opinion dated August 30, 1989 affirming a defense verdict in the federal multi-district litigation Bendectin trial, the Sixth Circuit Court of Appeals clearly acknowledged that the issue of whether Bendectin causes birth defects is clearly a jury question. The Court stated that "it is helpful to perspective to realize, as we observed earlier, that the jury verdict following trial here might have been for plaintiffs instead of defendant." Id. at 325. This case truly is "a classic battle of the experts, a battle in which the jury

must decide the victor." Oxendine, 506 A.2d at 1110, quoting, Ferebee, 736 F.2d at 1535; see also, Richardson, 857 F.2d at 826. Because of the District of Columbia Court of Appeals' myopic view of what is or is not admissible under Rule 703, the Court failed to recognize that this case presented the "classic battle," and jury verdict must stand.

In conclusion, in both Oxendine and Blum scientific and medical evidence was deemed sufficient by two state appellate courts to create a jury issue in Bendectin cases. So too, in Rosen, supra, and Lanzilotti, supra, a jury issue was created. By the admission of the defense's experts in

Oxendine, plaintiff's expert opinions were founded upon acceptable scientific methods. The Circuit Court in this case improperly applied Rule 703 to reach its desired result, without regard for the jury's traditional function. Furthermore, the District of Columbia Circuit Court improperly viewed the testimony in fragments, as opposed to recognizing its collective effect. The court in Oxendine and Blum, as well as Rosen and Lanzilotti, clearly found that medical and scientific evidence is sufficient to sustain a jury verdict. Richardson should be treated no differently, and Rule 703 does not dictate a contrary result.

CONCLUSION

Based upon the foregoing, amicus curiae respectfully requests that this Court grant Petitioner's Petition for Certiori.

Respectfully submitted,

ASSOCIATION OF BIRTH DEFECT CHILDREN

BEASLEY, CASEY, COLLERAN, ERBSTEIN, THISTLE, KLINE and MURPHY

BY: Thomas R. Kline
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CERTIFICATE OF SERVICE

I, THOMAS R. KLINE, ESQUIRE, hereby certify that on August 3, 1989, counsel listed below were served by with three true and correct copies of Motion for Leave to File Brief as Amicus Curiae and Amicus Curiae Brief of the Association of Birth Defect Children:

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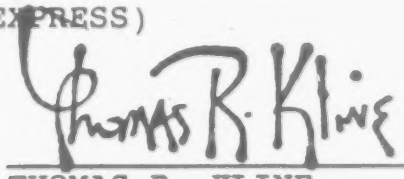

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